Sections Included in this Document and Change History

1. Purpose

To assure that records used by [Name] employees are properly managed. Records include reports, correspondence, diaries, quality records and technical records. Quality records include the following: internal audit reports, management reviews, corrective and preventive actions. Technical records include forms, worksheets, control graphs, inspection reports, and test reports.

2. Scope

This procedure applies to the management of records within the [Name]. Records may be either in hard copy or electronic form.

3. Responsibilities

A. [Third Level Manager]:

- verifies adequacy and accuracy of forms and worksheets used in their area,
- reviews report packets for completeness, and
- ensures employees are trained in record keeping.

B. [Second Level Manager]:

- implements record management system in respective branch,
- ensures proper forms and worksheets are used in respective branches, and
- follows established record storage and disposal schedule.

C. [First Level Manager]:

- ensures implementation of a record management system,
- ensures storage areas for records are within resources, and
- periodically assess the effectiveness of the record management system.

D. Quality System Manager (QSM):

- maintains record system for quality records, and
- archives and disposes of quality records as established by record schedule.

E. Record Clerk (Optional):

- maintains record system and databases,
- transfers records for archival as established by record schedule, and
- serves as principal custodian for the Records Management Center.
- In the absence of the record clerk, the alternates are the administrative support personnel for Investigations Branch. The alternates are responsible for checking in and out of records only.

F. Staff is:

- responsible for using the proper and approved forms and worksheets,
- responsible for following record management guidelines, and
- securing records (i.e. placing in locked cabinets) when in their possession.

4. Background

None.

5. References

Staff Manual Guide FDA SMG 3291.2, Field Office Filing System

6. Procedure

Procedure for identification, collection, indexing, access, filing, storage, maintenance and disposal.

A. Record Identification

1. Records are identifiable to the firm, product, person or event to which they pertain.

2. Records are dated and identify the person who established the record.

B. Recording and Error Correction

1. All work performed is recorded legibly. Work is recorded in such a manner than another individual, competent in the same field, may repeat the work described solely from the description written without additional explanation.

2. Entries contain the date, initials of person performing the work, signed and dated.

3. Entries are made in ink. No erasures are made. Space not used will be indicated with a line.

4. Corrections will be made by drawing a single line through the incorrect entry, enter the correct information, initial and date the change.

5. Data or information is not discarded without explanation. To discard, the data or information is crossed out, initialed, dated and the reason for discarding indicated.

C. Electronic Records

1. Electronic records and data files are backed up on a regular basis to safeguard against the loss of information due to equipment malfunctions or human error. Instrument backups are noted on the respective Function Verification and Preventive Maintenance sheet.

2. If applicable backups for the database in the Records Management Center (RMC) onto tape media are performed daily, weekly and monthly.

3. External labels of disk and diskettes or CDs are labeled to facilitate accurate filing and retrieval of electronic records. Examples of information that may be included on the label are:

    - subject or functional title which identifies the information,
    - inclusive dates of information contained on the diskettes or CDs, and
    - identification of the software program used to access the information.

D. Access

1. There is restricted access to all records to prevent unauthorized use and amending of information.

2. Access to the [Name] is restricted to authorized personnel ([Name] personnel or escorted visitors.

3. Records are returned during normal business hours to principal custodian or alternates.

4. Records to be filed in the [Location] are secured in the room at all times. This includes records that have been returned.

5. Electronic records have password or field protection, or read-only capabilities.

E. Filing and Storage

1. Records are stored in dry and clean rooms. Storage areas and cabinets are labeled. Records and other quality documents may not be stored in private desk drawers or other obscure locations that are not generally known.

2. Records pertaining to completed inspections and applications are filed in the [Location].

3. Records are filed by the [Filing Convention (e.g. sample identification number)].

4. Quality records (e.g. audits, archived procedures and work

instructions, corrective action and problem reports, function verification and preventive maintenance charts) are filed in the Quality System Manager's office.

5. Analytical worksheets except for Lab Class I microbiology import samples are returned to the home district and not stored by the analyzing laboratory in general.

F. Record Charge-Out

1. To charge out a record, [Procedure].

2. Records that are charged out are kept on the premises and kept secured (e.g. in a cabinet or drawer) when not being actively used.

3. To transfer a charge-out record, the file is returned and then transferred to the requested person.

G. Record Retention

1. The retention period will not be less than five years or as governed by regulation or policy. Quality records will be retained for a minimum for three years.

2. Reports will be stored in a secure location with limited access. Computer based files are archived and stored for record keeping.

3. The following information should be available in laboratory data files:

- date, place, time of sampling and name of person who collected,
- identification of sample as to whether it is a routine or check sample,
- date of receipt of sample and date of analysis,
- laboratory and persons responsible for performing analysis,
- analytical technique and method used and quality control data, and

- results of analysis.

H. Disposal of records

After the retention period is completed records will be destroyed or transferred to an agency storage facility, for example, the Federal Records Center (FRC). Disposal of documents is in accordance with guidelines described in agency policy statements and directives.

I. Archival of Quality Records

Laboratory Operating Procedures

1. Superceded and outdated laboratory operating procedures and work instructions (controlled copies) are archived as replaced. Archived hardcopy records are marked "ARCHIVED", dated and filed for the remaining time of the retention period.

2. The master list is updated and electronic files are moved to a directory titled "ARCHIVEDSOPS".

Other Quality Records

1. Quality records (e.g. audit reports, reviews, FV and preventive maintenance charts, quality control charts, corrective actions) are archived per calendar year. Only current year's records are kept in the applicable areas.

7. Definitions

Data file – A data file is related numeric, graphic or textual information that is organized in a strictly prescribed form and format.

Electronic record – An electronic record is information recorded in a form that only a computer can process. Electronic records include numeric, graphic and textual information.

Form – A form is a document with a fixed arrangement of captioned spaces designed for entering and extracting prescribed information. Forms become a record once filled out.

Non-record – Non-records are copies of memoranda or letters sent to an office or an employee for information only and for whose filing or maintenance no

one in the office is responsible.
Records – Records are materials created or received by an agency and that are preserved as evidence of the activities of the agency or for its information value.

Technical records – Technical records are accumulations of data and information which result from carrying out tests or calibrations and which indicate whether specified quality or process parameters are achieved.

Controlled copy – A controlled copy is a document that is numbered and issued to an individual, the contents of which will be updated after distribution.

Uncontrolled copy – An uncontrolled document is a document that is current at the time of issue but for which no attempt will be made to update it after distribution; document is marked "Uncontrolled Copy".

8. Records

None

9. Supporting Documents

None

10. Attachments

Attachment A: Records Schedule

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**
1.3	R	12/31/07	In Document	LMEB	LMEB
1.4	R	06/06/08	In Document	LMEB	LMEB
1.5	R	02/21/12	In Document	LMEB	LMEB
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Approving Official's signature: _____ Date: _____

Laboratory and related records, with their storage locations, retention periods and disposal, are maintained as follows:

RECORD	LOCATION	RETENTION	DISPOSAL
Sample files, Laboratory Control Documents and Analytical Worksheets	co	5 years	Destroy 5 years after action or analysis mpleted
No Action Indicated Samples Files		2 years	Destroy 2 years after date of collection
NDA/ANDA/NADA		5 years	Destroy after 10 years
Training Records		Retain for life of Employee or 5 years after departure	
Subcontractor Qualification	Purchasing	3 years	Destroy after 3 years
Work Orders	Purchasing	3 years	Destroy after 3 years
Audit Reports	QMS	3 years	Destroy after 3 years
Management Review	QMS	3 years	Destroy after 3 years
QA Calibration Records	QMS	3 years	Destroy after 3 years
Corrective Action Reports	QMS	3 years	Destroy after 3 years
Complaints and Comments	QMS	3 years	Destroy after 3 years
Method Validation and Modifications	QMS	3 years	Destroy after 3 years
Lab Procedures and Work Instructions	QMS	3 years	Destroy after 3 years
QA/QC Charts	QMS	3 years	Destroy after 3 years

NDA – New Drug Application
ANDA – Abbreviated New Drug Application
NADA – New Animal Drug Application
QA/QC - Quality Assurance/Quality Control